#18

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANTS : MICHAEL J. PAPPAS & FREDERICK F. BUECHEL

REGISTRATION NO.: 4,309,778

ISSUED : JANUARY 12, 1982

FOR : NEW JERSEY MENISCAL BEARING KNEE REPLACEMENT

CERTIFICATE OF MAILING BY EXPRESS MAIL

HONORABLE COMMISSIONER OF
PATENTS & TRADEMARKS
WASHINGTON, D.C. 20231

SIR:

I hereby certify that the attached APPLICATION FOR EXTENSION OF PATENT TERM PURSUANT TO 35 U.S.C. §156 together with our check in the amount of $750.00 in payment of the filing fee is being deposited this day, June 10, 1985, by Express Mail Post Office to Addressee service of the United States Postal Service in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, said Express Mail Post Office to Addressee bearing the No. B14458999.

Respectfully submitted,

Michael J. Pappas & Frederick F. Buechel, Applicants

By _____

JOHN G. GILFILLAN III
Reg. No. 22,746
CARELLA,BYRNE,BAIN & GILFILLAN
6 Becker Farm Road
Roseland, New Jersey 07068
(201)994-1700

Dated: June 10, 1985

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE U.S. PATENT NO. 4,309,778	APPLICATION FOR EXTENSION OF PATENT TERM PURSUANT TO 35 U.S.C. §156

Biomedical Engineering Trust of 153 Irvington Avenue, South Orange, New Jersey, 07079, being the owner of all right, title and interest in and to U.S. Patent No. 4,309,778, issued to Michael J. Pappas and Frederick F. Buechel on January 12, 1982 for NEW JERSEY MENISCAL BEARING KNEE REPLACEMENT, by its Trustees, hereby applies for an extension of the term of all claims of said patent pursuant to 35 U.S.C. §156.

In support of this application, applicant states:

1. The product forming the subject matter of U.S. Patent No. 4,309,788 has been subject to a regulatory review period by the U.S. Food and Drug Administration prior to its commercial marketing.

2. The approved product constitutes a total knee prosthetic incorporating the SLIDING MENISCAL BEARING OF THE NEW JERSEY TOTAL KNEE SYSTEM and THE ROTATING PLATFORM OF THE NEW JERSEY KNEE SYSTEM.

3. The regulatory review of the approved product was conducted pursuant to Section 515 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360(e).

4. The Food and Drug Administration granted permission for commercial marketing of the product on April 12, 1985. Copies of the Food and Drug Administration Approvals addressed to applicants' licensee are attached hereto as Exhibits A and B.

5. This application is being submitted within the sixty day period provided for in the statute, the last day for submission being June 11, 1985.

6. Attached hereto as Exhibit C is a copy of U.S. Patent No. 4,309,778, the patent for which an extension is being sought, mounted as required at 1047 OG 18.

7. The claims of U.S. Patent No. 4,309,778 are directed to the approved product in that each of Claims 1-48 defines an improved prosthetic knee joint incorporating features such as means for constraining motion of a bearing insert means during joint articulation to a predetermined path relative to a tibial platform means, which structure was incorporated in the knee joint forming the subject matter of the premarket approval application.

8. The dates and information required pursuant to 35 U.S.C. §156(g) from which the Secretary of Health and Human Services can determine the applicable regulatory review period are shown in Exhibits A and B (date of approval for commercial marketing was April 12, 1985) and Exhibit D (chronology of new Jersey Knee Clinical Investigation).

9. During the regulatory review period applicant continued clinical studies and developed data necessary to satisfy the requirements of the Food and Drug Administration. A chronology reflecting applicants' activities is presented in Exhibit D.

10. In the opinion of applicants the patent is eligible for an extension of three (3) months, that period being the period between January 12, 1999, the unextended expiration date of the patent, and April 12, 1999, the date fourteen (14) years subsequent to the date of approval for commercial marketing by the Food and Drug Administration.

11. Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to any determinations to be made relative to this application for extension.

The undersigned, being all the trustees of Biomedical Engineering Trust, declare that:

(a) They have reviewed and understand the contents of this application;

(b) They believe that U.S. Patent No. 4,309,788 is subject to extension pursuant to 35 U.S.C. §156 and 1047 OG 16§A, and that the proper extension is three months; and

(c) They believe that U.S. Patent No. 4,309,788 meets the conditions set out in the Official Gazette Notice at 1047 OG 17§B.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize this application.

Date: June 7, 1985 — Michael J. Pappas
MICHAEL J. PAPPAS

Date: June 7, 1985 — Frederick F. Buechel
FREDERICK F. BUECHEL

POWER OF ATTORNEY

Michael J. Pappas and Frederick F. Buechel, Trustees of BIOMEDICAL ENGINEERING TRUST hereby appoint CARELLA, BYRNE, BAIN & GILFILLAN, 6 Becker Farm Road, Roseland, New Jersey 07068, Telephone No. 201-994-1700, and in particular John G. Gilfillan III, Reg. No. 22,746 and John N. Bain, Reg. No. 18,651, our attorneys with full power of substitution and revocation, to prosecute and transact all business in the Patent and Trademark Office connected with this application. All correspondence is to be addressed to Carella, Byrne, Bain & Gilfillan, 6 Becker Farm Road, Roseland, New Jersey 07068 (Attn: JOHN G. GILFILLAN III, ESQ.).

Date: June 7, 1985

Michael J. Pappas
MICHAEL J. PAPPAS

Date: June 7, 1985

Frederick F Buechel
FREDERICK F. BUECHEL

Exhibit A II

Revised: March 28, 1984

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of all approved labeling in final printed form to the Food and Drug Administration (FDA), Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Advertisement. No advertisement for this device shall recommend or imply that the device may be used for any use that is not mentioned in the approved labeling for the device. All written promotional material shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

Premarket Approval Application (PMA) Supplement. Before making any change that may affect the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA. Such changes include, but are not limited to:

(1) new indications for use;

(2) labeling changes;

(3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;

(4) changes in sterilization procedures;

(5) changes in packaging; and

(6) changes in the performance or design specifications, circuits, parts, components, accessories, ingredients, or physical layout of the device.

Changes in labeling, manufacturing, sterilization, packaging, or performance of design specification which enhance safety of the device or safety in the use of the device may be placed into effect by the sponsor before the receipt of a written FDA approval of the PMA supplement provided:

(1) the submission is plainly marked on the mailing cover and on the PMA supplement "Special PMA Supplement - Changes Being Effected";

(2) the PMA supplement provides a full explanation of the basis for the changes;

(3) the applicant has received acknowledgement of FDA receipt of the PMA supplement; and

(4) the PMA supplement specifically identifies the date that such changes are being effected.

Specific examples of changes permitted are the following:

(1) addition of warnings, contraindications, or side effects;

(2) deletion of misleading, false, or unsupported indications; and

(3) changes in the manufacturing process or quality controls that provide additional assurance of purity, identity, strength, or reliability.

FDA may, as experience permits, issue guidelines listing specific types of changes that do not require FDA approval before implementation.

Post-Approval Reports. Continued approval of your device is contingent upon the submission of post-approval reports to the Food and Drug Administration (FDA), Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910 at intervals of 1 year from the date of this letter. The required contents of these reports will be described in the FEDERAL REGISTER in the premarket approval procedural regulation which will be published in the future. Until this regulation is published in final form, each periodic report shall consist of information that previously has not been submitted as part of a PMA or PMA supplement and which you have obtained since the last post-approval report or since receipt of this letter, whichever is later:

(1) a summary and bibliography of reports in the scientific literature involving the device and unpublished reports of in vitro, animal and clinical experience studies, investigations, and tests conducted by, reported to, or reasonably available to you involving the device or a related device--if, after reviewing the summary and bibliography, FDA concludes that it needs a copy of the published and unpublished reports, FDA will notify you that copies of such reports shall be submitted;

(2) written promotional material; and

(3) a description of changes made in the device not previously submitted in a PMA supplement.

Adverse Reaction and Device Defect Reporting.

You shall submit a written report to the Food and Drug Administration (FDA), Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910 within 10 days after you receive or have knowledge of information about:

(1) a mixup of the device or its labeling with another article;

(2) any significant chemical, physical, or other change or deterioration in the device, or any failure of one or more of the devices to meet the specifications established in the application;

(3) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has not been addressed by the device's labeling; and

(4) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

Note: All conditions of approval are subject to change upon publication of a final premarket approval regulation.

Exhibit B

B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

RECEIVED

APR 18 1985

DePUY REGULATORY AFFAIRS

APR 12 1985

Re: P830055
The Rotating Platform of
The New Jersey Total Knee
System
Filed: August 16, 1983
Amended: February 9, June 4
and 12, August 24, September 26,
October 29, and November 23,
1984; January 8, March 11,
April 1, 8 and 9, 1985

Mr. Joseph G. Bagwell
Vice President, Regulatory Affairs
and Quality Assurance
DePuy® Incorporated
A Boehringer Mannheim
Company
P.O. Box 988
Warsaw, Indiana 46580

Dear Mr. Bagwell:

FDA has completed its review of your premarket approval application (PMA) for The Rotating Platform of The New Jersey Total Knee System. The device is indicated for cemented use in cases of osteoarthritis, rheumatoid arthritis, and for revision of failed knee prostheses. The Rotating Platform of The New Jersey Total Knee System is indicated for patients who are 41 years of age or older. The safety and effectiveness of the device for patients of age less than 41 years are unknown and remain under investigation. The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin production and marketing of the device upon receipt of this letter.

FDA will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved final labeling (which may be a draft of the final labeling) is available for public inspection at the Center for Devices and Radiological Health. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (act).

1. The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act.

2. A clinical post-market surveillance program must be implemented that allows for follow-up of a sufficient number of patients out to a 5-year anniversary date such that the data will include the clinical performance of 100 patients of the Rotating Platform. The patient selection technique to be used for the post-market surveillance will include the cases that have already reached at least an 18-month post-surgery date with a proportion of cases chosen from each investigational site based on the proportions found in PMA P830055. Beyond this criteria, selection will be a random choice of patient identification numbers with no bias as to the current clinical status of the case. The reports will include an analysis of clinical parameters, complications and device defects for all cases reported on from the date of surgery. Those cases in the post-market surveillance program that become lost to follow-up must be accounted for in the report.

All stated requirements are subject to change upon publication of a final premarket approval procedural regulation. Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You shall submit all required documents in triplicate to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910. You shall refer to the above PMA number in all further correspondence to expedite processing.

If you have any questions concerning this approval order, please contact Carl A. Larson, Ph.D., at (301) 427-7156.

Sincerely yours,

Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Revised: March 28, 1984

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(3) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has not been addressed by the device's labeling; and

(4) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

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D

Exhibit C

CHRONOLOGY OF
NEW JERSEY KNEE
CLINICAL INVESTIGATION

Investigational Device Exemption Submitted	7/14/80
Amendment 1 - Production, Q. C., Protocol Validity	10/06/80
Amendment 2 - Sterility	2/05/81
Amendment 3 - Sterility	4/21/81
Investigational Device Exemption Approval	5/26/81
First Patient Entered After Approval	5/26/81
IDE Supplement - Patient Population	2/15/82
Approved	3/22/82
IDE Supplement - Revisional Component	6/25/82
Approved	7/27/82
IDE Supplement - Investigator Additions	4/25/83
Approved	6/10/83
IDE Supplement - Control Group	5/11/83
Approved	6/10/83
IDE Supplement - Data Reduction	10/06/83
Not Approved	11/29/83
Pre-Market Approval Application Submitted	8/12/83
PMA Amendment - Summary, Clinical Data, Mfg., Labeling	2/03/84
PMA Amendment - Labeling, Sterilization	5/25/84
PMA Amendment - Clinical Data	6/08/84
PMA Amendment - Wear Testing, Sterilization	8/20/84
PMA Amendment - Data Statistics	9/26/84
PMA Amendment - Wear Testing, Labeling	10/25/84
PMA Amendment - Sterilization, Post-Market Clinical	11/09/84
PMA Amendment - Sterilization	1/07/85
PMA Supplement - Submission Rearrangement	3/08/85
PMA Supplement - Labeling	4/16/85
PMA Approval	4/25/85